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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,070	07/10/2003	Matt Neville	FORS-08195	8224

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MEDLEN & CARROLL, LLP
101 HOWARD STREET
SUITE 350
SAN FRANCISCO, CA 94105

EXAMINER	
JOHANNSEN, DIANA B	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/617,070	NEVILLE ET AL.	
	Examiner	Art Unit	
	Diana B. Johannsen	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-10, drawn to a kit comprising an "oligonucleotide detection assay," classified in at least, for example, class 536, subclass 24.31.

   II. Claims 11-17, drawn to a method for detecting a CYP2D6 genotype, classified in at least, for example, class 435, subclass 6.

   III. Claims 18-24, drawn to a method for genotyping, classified in at least, for example, class 702, subclass 20.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II, and I and III, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the oligonucleotides encompassed by Invention I may be used in materially different processes, such as nucleic acid sequencing or mapping.

Additionally, searching the inventions of Groups I and II together, and/or I and III together, would impose a serious burden. Each of the 3 Inventions has a separate status in the art as evidenced by its separate classification. Further, the searches required by Inventions I and II, and I and III, are different and not coextensive. Inventions II and III require searches for methods having particular steps: for example,

Invention II requires a search for a method in which a sample is exposed to a "detection assay," while Invention III requires a search for a method in which a genotype profile is generated and compared to an "information matrix." In contrast, Invention I requires a search for a kit comprising oligonucleotides, control reagents, etc.

Inventions II and III are patentably distinct methods employing different reagents in different method steps to achieve distinct objectives. Invention II requires a step of, e.g., exposing a sample to a "detection assay" to achieve the objective of detecting a CYP2D6 genotype, while Invention III requires steps of, e.g., generating a genotype profile and comparing that profile to an "information matrix" to achieve the objective of genotyping. As discussed above, Inventions II and III are also separately classified and require different searches that are not coextensive; accordingly, a search of the two Inventions together would impose a serious burden.

Election Requirements Applicable to Groups I - III

3. A further restriction required is applied to each of Groups I-III as follows:

a) Group I is drawn to kits that are "configured to identify the presence or absence of at least two CYP2D6 associated polymorphisms" (see claim 1), which polymorphisms may be selected from the list of 32 different polymorphisms recited in dependent claim 4 (a subset of which are also recited in claim 9). Each such combination of "at least two" polymorphisms possesses different structural and functional characteristics; the combinations are not, e.g., obvious variants that may be substituted one for the other. Further, a search of more than one such combination would impose a serious burden, as each combination would require a sequence and

text search different from that of every other such combination. Accordingly, **if Group I is elected, Applicant is further required to elect a single combination of "at least two" polymorphisms, which polymorphisms may be selected from those set forth in dependent claim 4.**

This is not an election of species. Applicant is advised that examination will be restricted to the elected combination of polymorphisms.

b) Group II is drawn to methods that require the detection of "at least two CYP2D6 polymorphic sequences" (see claim 11), which polymorphic sequences may be selected from the list of 32 different sequences recited in dependent claim 15 (a subset of which are also recited in claim 17). Each such combination of "at least two" polymorphic sequences possesses different structural and functional characteristics; the combinations are not, e.g., obvious variants that may be substituted one for the other. Further, a search of more than one such combination would impose a serious burden, as each combination would require a sequence and text search different from that of every other such combination. Accordingly, **if Group II is elected, Applicant is further required to elect a single combination of "at least two" polymorphic sequences, which sequences may be selected from those set forth in dependent claim 15.**

This is not an election of species. Applicant is advised that examination will be restricted to the elected combination of polymorphic sequences.

c) Group III is drawn to methods that require the detection of "at least 25 single nucleotide polymorphisms associated with the CYP2D6 gene" (see claim 18), which polymorphisms may be selected from the list of 32 different polymorphisms

recited in dependent claim 20 (a subset of which are also recited in claim 21). Each such combination of polymorphisms possesses different structural and functional characteristics; the combinations are not, e.g., obvious variants that may be substituted one for the other. Further, a search of more than one such combination would impose a serious burden, as each combination would require a sequence and text search different from that of every other such combination. Accordingly, **if Group III is elected, Applicant is further required to elect a single combination of polymorphisms, which polymorphisms may be selected from those set forth in dependent claim 20.**

This is not an election of species. Applicant is advised that examination will be restricted to the elected combination of polymorphisms.

4. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, and require different searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner, and therefore restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance,

whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is

571/272-0744. The examiner can normally be reached on Monday and Thursday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571/272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Diana B. Johannsen
Primary Examiner
Art Unit 1634

2/20/06